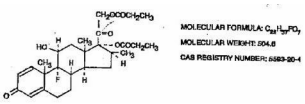
BETAMETHASONE DIPROPIONATE - betamethasone dipropionate lotion
Perrigo New York, Inc.

(potency expressed as betamethasone)
Rx only

DESCRIPTION

Betamethasone Dipropionate is a synthetic adrenocorticosteroid, for dermatologic use. It is used as an anti-inflammatory and anti-pruritic agent. Betamethasone Dipropionate is the 17, 21-dipropionate ester of betamethasone, and has the chemical name: 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate.



Each gram of Betamethasone Dipropionate Lotion USP, 0.05% w/w contains: 0.64 mg Betamethasone Dipropionate, USP (equivalent to 0.5 mg betamethasone), in a lotion base of Isopropyl alcohol (46.8%), purified water, carbomer 934P, and sodium hydroxide to adjust pH to approximately 4.7.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, anti-pruritic, and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroid. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. (see **DOSAGE AND ADMINISTRATION**)
Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. (see **DOSAGE AND ADMINISTRATION**)
Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Topical corticosteroid are indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.
Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. (see **DOSAGE AND ADMINISTRATION**)
Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.
Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.
Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See **PRECAUTIONS-Pediatric Use**).
If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.
In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient
Patients using topical corticosteroids should receive the following information and instructions:
(1) This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes. (2) Patients should be advised not to use this medication for any disorder other than for which it was prescribed. (3) The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive. (see **DOSAGE AND ADMINISTRATION**) (4) Patients should report any signs of local adverse reactions. (5) Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings. (see **DOSAGE AND ADMINISTRATION**)

Laboratory Tests
The following tests may be helpful in evaluating HPA axis suppression: Urinary free cortisol test and ACTH stimulation test.

Carcinogenesis, Mutagenesis, and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy

Teratogenic Effects

Pregnancy Category C
Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to nursing women.

Pediatric Use
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.
Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.
Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids when used as recommended.
These reactions are listed in an approximate decreasing order of occurrence: Burning, Itching, Irritation, Dryness, Folliculitis, Hypertrichosis, Acneiform Eruptions, Hypopigmentation, Perioral Dermatitis, Allergic contact dermatitis, Maceration of the skin, Secondary infection, Skin Atrophy, Striae, Miliaria.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See **PRECAUTIONS.**)

DOSAGE AND ADMINISTRATION
Betamethasone Dipropionate Lotion USP, 0.05%: Apply a few drops to the affected area and massage lightly until it disappears. Apply twice daily, in the morning and at night. For the most effective and economical use, apply nozzle very close to the affected area and gently squeeze bottle.
Betamethasone Dipropionate Lotion USP, 0.05% is not to be used with occlusive dressings.
If an infection develops, appropriate antimicrobial therapy should be instituted.

HOW SUPPLIED
Betamethasone Dipropionate Lotion USP, 0.05%: Available in 20 mL (18.7 g) and 60 mL (56.2 g) plastic bottles. Protect from light. Store in carton until contents are used.

Store between 15°-30° C (59°-86° F)
For Dermatological Use Only. Not For Ophthalmic Use. Keep Out of the Reach of Children.

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